



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
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October 31, 2008

Reply To: OEA095

MEMORANDUM

DRAFT

**SUBJECT: Risk Assessment Approach for Evaluating Potential Risks
From Consuming Human Milk**

FROM: Michael Cox
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TO: Risk Assessors on Projects in EPA Region 10

INTRODUCTION

Risk assessors in the Risk Evaluation Unit of the Office of Environmental Assessment (OEA) are advocating that potential risks from consumption of human milk be included in risk assessments of bioaccumulating chemicals. **If breastfeeding is a relevant pathway at a site, the hazard quotient for the infant from PCB exposure is more than an order of magnitude greater than the hazard quotient for the mother.** This memorandum presents a standard approach for evaluating the breast feeding exposure pathway.

EPA evaluated the feasibility of conducting a risk assessment based on exposure to human milk using EPA's *Human Health Risk Assessment Protocol for Hazard Waste Combustion Facilities*¹ (Combustion Guidance), *Exposure Factors Handbook*², *Child-Specific Exposure Factors Handbook*³, and examples from other hazardous waste sites. OEA toxicologists determined that it is feasible to include exposure to human milk in human health risk assessments, and that this is an important exposure pathway for bioaccumulating chemicals. Beginning on _____ 2008, all risk assessments performed for EPA Region 10 that include one or more of the bioaccumulating chemicals shown in Table 1 should include potential risks from the breast feeding pathway.

¹ U. S. EPA. *Human Health Risk Assessment Protocol for Hazard Waste Combustion Facilities*. (EPA 530-R-05-006, September 2005).

² U.S. EPA. *Exposure Factors Handbook*. National Center for Environmental Assessment, Office of Research and Development. August 1997.

³ U.S. EPA. *Child-Specific Exposure Factors Handbook*. National Center for Environmental Assessment, Office of Research and Development. EPA-600-P-00-002B. September 2008.

To assist risk assessors in incorporating the human milk consumption pathway into the human health risk assessment, OEA toxicologists prepared the attached memorandum to present the relevant exposure and risk equations, and exposure and toxicity parameters. They include example calculations using total polychlorinated biphenyls (PCBs) to show how the various equations in EPA's combustion guidance can be modified to focus on ~~the~~ fish consumption, one of the most important exposure pathways for bioaccumulating chemicals. Actual risk assessments should include the exposure pathways relevant for the site. The risk assessments should also include all relevant chemicals, such as total PCBs (from Aroclors or congeners), 2,3,7,8-TCDD equivalents (from chlorinated dibenzo-*p*-dioxins, chlorinated dibenzofurans, and dioxin-like PCB congeners, evaluating each chemical class separately and collectively as the sum of all dioxin-like chemicals), and DDT and its degradation products.

Risk assessments can incorporate the human milk exposure pathway by simply applying the relative risk ratios provided by EPA in Table 1. These values can be used to calculate the potential risk to infants based on calculated risks to the mother, which should already be evaluated for relevant exposure pathways. **The relative risk ratios are independent of the exposure pathway or dose to the mother, and apply to every site where there is exposure to bioaccumulating chemicals.** The use of relative risk ratios will simplify incorporation of the breast feeding pathway into risk assessments.

Generally, risk assessments are limited to an evaluation of risk, and do not consider comparative risks or benefits. For example, eating fish is health beneficial compared with eating other protein sources. Public health agencies commonly address the health tradeoffs of eating contaminated fish, but the issue is not typically discussed in a Superfund risk assessment. For breast feeding, however, the benefits to infants are so substantial that we consider it appropriate to discuss the issue in the risk assessment. The Oregon Environmental Health Assessment Program (EHAP) has prepared a letter that presents the risks and benefits of consuming contaminated human milk. This letter has been reviewed by the Agency for Toxic Substances Control (ATSDR) and is included as an appendix to the attached memorandum. We recommend that information presented in the appendix be included with risk assessments that include the breast feeding pathway.

Table 1
Default Ratios for Calculating Human Milk Consumption Risks Based on Risks
Calculated for Exposure to the Mother

Chemical	Ratio to Convert Chronic HQ for Mother to Subchronic HQ for Infant	Ratio to Convert ELCR for Mother to ELCR for Infant
CDDs/CDFs	10	1
DDT	1	1
Total PCB	30	2
PCB TEQ	-	2

Notes:

HQ = hazard quotient

ELCR = excess lifetime cancer risk

CDD = chlorinated dibenzo-*p*-dioxin

CDF = chlorinated dibenzofuran

DDT = dichlorodiphenyltrichloroethane

PCB = polychlorinated biphenyl

TEQ = 2,3,7,8-tetrachlorodibenzo-*p*-dioxin toxicity equivalent